REMARKS

Claims 1-26 are currently pending. Applicant respectfully requests that the above application be reconsidered, as amended. Further, Applicant submits herewith a Declaration traversing rejections under 37 CFR §1.132. The Declaration further explicates the ratios between the distal, intermediate and proximal portions of the tube of the present invention, evidencing the criticality of the ratios, which is not taught, suggested, or motivated in the cited references.

Applicant asserts that the claims as amended are fully supported in the application as originally filed and contain no new matter, and respectfully request reconsideration for the following reasons.

I. Claim Rejections under 35 USC §102(b) – rejection of Claims 1, 3-11, 15, and 17

Claims 1, 3-11, 15, and 17 remain rejected under 35 USC §102(b) as anticipated by Beck, Jr. et al., US Patent No. 5,339,809 ("Beck"). The Examiner disagrees with the Applicant's previous argument that Beck discloses an elongated distal end tube section 2 in direct contrast to Applicant's short distal section, and that Beck discloses a short proximal tube section 12 in direct contrast to Applicant's elongated proximal section.

According to the Examiner, Beck allegedly discloses a short distal section of tubing, even though Beck characterizes its distal section as "elongated," see Beck Claim 1, and an elongated proximal section of tubing, even though FIG. 2 of Beck illustrates that Beck's proximal tube section 12 is the shortest of the other sections of the tube. Further, the Examiner now alleges that the Applicant fails to describe "how short/elongated", or "short/elongated to what," such that the terms 'short' and 'elongated' "are considered broad terms in which the Beck reference reads on."

Although the Applicant respectfully disagrees, nevertheless the Applicant has amended independent Claims 1 and 17 in order to better define the terms 'short' and 'elongated' as they apply to the distal and proximal sections of the tube, respectively. Specifically, the phrase "wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0, and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0" has been added to independent Claims 1 and 17. That is, using the ratios claimed by the Applicant, the elongated proximal section must be between about 2 to about 4 times longer than the short distal section, and the short distal section must be between about equal

to and about twice the length of the intermediate section. Thus, the distal section of the Applicant's tube, besides being termed 'short,' now also has required parameters within which it must fit in order to be considered 'short.' Likewise the elongated proximal section of the Applicant's tube also has required parameters which validate its being termed 'elongated.'

Since amended Claims 1 and 17, as well as their depending claims including Claims 3-11 and 15, now include a definitive comparison between the short distal, intermediate, and elongated proximal sections, the Applicant asserts that the claims as amended now sufficiently define the meaning of the comparative terms 'short' and 'elongated,' and leaves no doubt that Beck's elongated distal section does not read on the Applicant's short distal section, and that Beck's shortest of all sections, the proximal section, does not read on the Applicant's elongated proximal section, since the ratios of the sections of the Beck tube do not fit within the parameters claimed by the Applicant.

In summary, to anticipate a claim, the cited reference must disclose each limitation of the claim at issue. Beck does not disclose all of the limitations of Applicant's Claim 1, since in Beck the ratio of the length of the distal section to the length of the intermediate section is not from about 1.0 to about 2.0, and in Beck the ratio of the length of the proximal section to the length of the distal section is not from about 2.0 to about 4.0. Rather, the distal end tube section 2 of Beck is elongated, and the proximal tube section 12 of Beck is comparatively short. These are limitations that are not disclosed by Beck but are recited in Applicant's Claim 1, as well as in Claims 3-11, 15, and 17, of the present invention. As such, Beck does not disclose each limitation of Claims 1, 3-11, 15, and 17.

II. Claim Rejections under 35 USC §103(a) – rejection of Claims 2, 12, 18-20, 23-25

Claims 2, 12, 18, 19, 20, 23, 24, and 25 remain rejected under 35 USC §103(a) as allegedly being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Nye, US Patent No. 5,590,647 ("Nye"). The Examiner disagrees with the Applicant's previous argument that Nye teaches away from a flexible tube that is entirely made of a flexible thermoplastic material preformed to the shape described. Rather, Examiner alleges that Nye clearly states that at least one portion be made of flexible material, not ruling out that the entire tube be made of a flexible

material. The Applicant respectfully disagrees, and asserts that the Examiner is confused over the term 'flexible,' which is used in two distinctly different ways in Nye.

Nye's use of the term 'flexible' is a relative term, and the definition attributed by the Examiner is different and inapposite as it relates to the phrase "flexible thermoplastic material" in the present application. Specifically, Nye discloses a tube made of: (1) relatively non-flexible proximal and distal portions made of a flexible thermoplastic material having sufficient memory or resilience to return to the preformed shape following flexure, and (2) a truly flexible intermediate portion, made of material which allows for acute bends while maintaining constant connection to the other portions of the tracheal tube. The first definition of 'flexible' above relates to material which is similar if not identical to that used for the tube of the present application, while the second type of flexible material disclosed by Nye is truly flexible and moldable, and is not intended in the present application.

More specifically, Claim 1 of Nye recites "a distal end portion; ...a flexible intermediate portion; ...and a proximal portion." (Emphasis added). In the Detailed Description, referring to the relatively non-flexible distal and proximal portions of the tube, at column 6, lines 1- 14, Nye states:

> The distal end portion 20, and the proximal end portion 40, of tracheal tube 10, may be preformed from any suitable material having sufficient memory or resilience to return to the preformed shape following flexure. In particular, the distal end portion 20, should be made of a material which enables it to conform to the posterior pharynx and trachea of the patient, rather than forcing the posterior pharynx and trachea to conform to the tracheal tube. Further, the material should be such that the distal end portion 20, and proximal end portion 40, retain their configuration and do not kink during use. **Flexible thermoplastic materials such as polyvinylchloride, polyethylene, or the like** are preferred materials meeting all of the above requirements. (Emphasis added)

In the present application, the material intended for use matches Nye's definition of the relatively non-flexible material:

> The endotracheal tube herein is typically integrally preformed from a suitable **flexible thermoplastic material, such as polyvinylchloride, polyethelyne, or the like**, having a memory, i.e., having sufficient resiliency to return to position following flexure. (See paragraph 38 of the Applicant's published application, US 2004/0123869 ("the published application")) (Emphasis added)

Indeed, the truly flexible portion intended by Nye is the "flexible intermediate portion" of the tube, which is **more flexible than** the distal or proximal ends. The more flexible material of Nye is needed to solve the perceived problems associated with having the entire tube made of a flexible thermoplastic material that returns to its pre-formed shape following flexure. This truly flexible tube portion is further described in the Detailed Description, at column 6, lines 18 - 27:

> Flexible portion 30, or 130, may be formed of any suitable flexible material which allows for acute bends while maintaining constant connection to the other portions of the tracheal tube 10, or 100. This material must be capable of such bends without kinking or transferring unnecessary force to the proximal end portion 40, or the distal end portion 20, while maintaining constant inside and outside diameters. In a preferred embodiment, flexible portion 30, or 130, is formed from either expanded polytetrafluoroethylene (PTFE) tubing or a polyethylene material (any grade).

Thus the preferred material for the flexible portion of the Nye tube is completely different than the preferred material for the present invention.

Further, it is evident that Nye teaches away from a tube made entirely of a thermoplastic material preformed to the shape described, by pointing out that preformed tubes have disadvantages that the truly flexible portion overcomes, at column 2, line 61 – column 3, line 13:

> [T]he curve of the preformed tubes must be controlled accurately to correspond with the anatomy of the patient. While standard sizes and shapes will be appropriate for most patients, there are many occasions when the predetermined curve will leave the proximal extension at an improper distance from the facial region. This may result in excessive pressure being exerted on sensitive tissue in the nasal and oral regions, as well as to the mucosa and trachea at the distal end of the tracheal tube. [...] Also, the preformed tracheal tubes do not allow for shifting of the tube during an operation, but rather may be positioned in only one way. (Emphasis added)

The flexibility feature of the tube disclosed by Nye is thus not a result of the entire tube being in a preformed shape, as is the present invention, but rather Nye teaches a tube having a truly flexible portion that allows for movement of the proximal end relative to the distal end of the tracheal tube without creating stress at the proximal or distal ends. This truly flexible material "allows easy relocation of the proximal end of the tube without requiring disconnection of the anesthesia circuit," and allows "the tube to be easily moved and located in an infinite number of

positions," (See Nye's Summary of the Invention, lines 33-40), and is not intended in the present application.

To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. Claims 2, 12, 18 and 23 recite: "wherein all sections and bends of the flexible tube are made of a thermoplastic material preformed to the shape described." In light of the above, Applicant contends that not all of the limitations of the claims have been met by the above-cited references, neither individually or in combination, since Nye teaches away from having the entire tube made of a thermoplastic material preformed to the shape desribed. Therefore, the rejection fails to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection be withdrawn and Claims 2, 12, 18, 19, 20, 23, 24, and 25, as amended, be duly allowed.

III. Claim Rejections Under 35 USC §103(a) – rejection of Claims 13, 14, 16, 21, and 22

Claims 13, 14, 16, 21, and 22 remain rejected under 35 USC §103(a) as being unpatentable over Beck, Jr. et al., US Patent No. 5,339,809 ("Beck") in view of Joseph, US Patent No. 5,582,167 ("Joseph"). Examiner alleges that Beck discloses the invention with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate, and that Joseph teaches a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Applicant respectfully disagrees.

First, in light of the current amendments to independent claims 1 and 17, above, Applicant asserts that Beck does not disclose the invention with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Second, Applicant asserts that Joseph does not teach a tracheostomy tube that provides a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate.

While FIG. 1 of Joseph illustrates an endotracheal tube with what the Examiner construes as an alleged eye or port adjacent to a beveled terminal end, the "port" depicted is never labeled or discussed further in the specification, and is not part of the claimed invention. Rather, Joseph is concerned more about disclosing an irrigation channel that delivers liquids such as saline or

antibiotic and antifungal medications for mucosal hydration, and bactericidal action against infected subglottic secretions. An outer sleeve surrounding the endotracheal tube forms a suction lumen for removing the secretions. Electronic and mechanical controls provide regulated volume infusion and regulated suction. (See Abstract of Joseph).

To articulate a *prima facie* case of obviousness, the art cited against the pending claims must teach all the limitations of the rejected claims. The prior art must also provide a motivation to combine those references to achieve the claimed invention, and provide to the skilled artisan a reasonable expectation of success in achieving the claimed invention. In light of the above remarks, it is readily apparent that neither Beck nor Joseph teaches a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Simply depicting in an illustration what may or may not be perceived as a "port," with no labeling, description, or explanation in the specification or claims, does not adequately provide the required motivation to combine the reference with another. Therefore, since none of the cited references expressly or implicitly teach or suggest, individually or in combination, all of the limitations of the rejected claims, or provide any motivation for one of ordinary skill in the art to modify the references or to combine the referenced teachings, the proposed combinations described above fail to articulate a *prima facie* case of obviousness. Applicant therefore respectfully requests the rejection be withdrawn and Claims 13, 14, 16, 21, and 22 be duly allowed.

IV. The Ratios Between the Sections of Tubing are Not a Simple Matter of Design Choice

With reference to Claims 23 and 26, the Examiner reasserts that the ratio between the length of the distal section to the length of the intermediate section, and the ratio between the length of the proximal section to the length of the distal section, are a simple matter of design choice. Applicant respectfully disagrees, since these ratios are important to the function of the claimed tube, relating to the anatomy of the average patient, adult or child, male or female, requiring a tracheotomy.

Attached hereto as Exhibit 1 is an Affidavit from the inventor, Dr. Michael Rutter, explaining how the claimed ratios are important to the function of the claimed tube, and are not matters of design choice. Thus, currently amended independent claims 1 and 17, as well as independent claim 23 and dependent claim 26, include these ratios.

Specifically, Dr. Rutter used typical anatomical measurements seen by him in his extensive clinical practice to create these claimed ratios. These ratios are thus not a matter of design choice, but are necessary to function as Dr. Rutter intended.

Typical distances exist (for both adults and children) for the following anatomical reference points: the distance from stoma site in the trachea to the carina (covered by the distal section of the tube); the distance from the inner trachea to the chest wall (covered by the intermediate section of the tube); and the distance from the stoma site at the chest wall to the oxygen source (covered by the proximal section of the tube). Dr. Rutter notes that typically a 2 year-old patient requiring a tracheostomy has a distance of between about 6 cm to about 8 cm from the stoma site in the trachea to the carina (the carina being the bifurcation point of the trachea into the bronchial tree), a distance of between about 4 cm to about 6 cm from the inner trachea to the chest wall, and a distance of between about 20 cm to about 24 cm from the chest wall to the oxygen source (which would be positioned away from the patient during surgery, as explained below). Similarly, in an 8 year-old patient, there is a distance of between about 8 cm to about 10 cm from the stoma site in the trachea to the carina, a distance of between about 5 cm to about 8 cm from the inner trachea to the chest wall, and a distance of between about 24 cm to about 28 cm from the chest wall to the oxygen source. Finally, in a typical adult patient (male or female), there is a distance of between about 10 cm to about 12 cm from the stoma site in the trachea to the carina, a distance of between about 6 cm to about 10 cm from the inner trachea to the chest wall, and a distance of between about 30 cm to about 35 cm from the chest wall to the oxygen source.

With all of these distances provided by Dr. Rutter, which he states are important to the proper use and function of his claimed tube, there is a common thread wherein the ratio of the length of the distal section to the length of the intermediate section is from about 1.0 to about 2.0, and the ratio of the length of the proximal section to the length of the distal section is from about 2.0 to about 4.0. further, as claimed in Claim 26, these claimed ratios can be narrowed such that the ratio of the length of the distal section to the length of the intermediate section is from about 1.2 to about 1.8, and the ratio of the length of the proximal section to the length of the distal section is from about 2.5 to about 3.5.

If the claimed ratios are not used then there is an increased likelihood for untoward events to occur. For example, the short distal section is necessarily short to avoid endobronchial intubation,

and the intermediate section is necessarily short to precisely fit the length of the stoma site between the chest wall and the esophagus. Since the intermediate section is needed to cover the distance between the trachea and the chest wall, which is a short distance in the average human, this section is the shortest section of tubing. The claimed ratios reflect this fact. Further, the distal section is also short, typically about the same length as, or slightly longer than, the intermediate section, since the distal section of the tube must be shorter than the distance between the stoma and the bronchi to prevent endobronchial intubation. The disclosed ratios reflect this as well.

Regarding the proximal section, it is important during surgery for the anesthesiologist to have access to the patient's airway. If the surgeon is operating in the mouth or upper airway, then the anesthesiologist is relegated to place the anesthesia machine in an area of the operating room that is located an uncomfortable distance away from the patient's upper airway. Thus, if the proximal section of the tracheostomy tube is elongated, as is claimed in the present application, then the anesthesiologist can easily access the connection of the tube to the anesthesia machine, which carries oxygen to the patient. Therefore the proximal section of tubing is necessarily elongated in order to allow the anesthesiologist access to the tube and to keep the tube away from the body cavity of the patient during use (See page 2, para. 32 of the published application). For this reason, the proximal section generally is at least twice as long as the distal section, and typically is about three times as long as the distal section (page 2, para. 34).

The published application notes that the tracheotomy endotracheal tube of the invention is useful for individuals of all ages. (See page 2, para. 28 of the published application) "The length of the distal, intermediate, and proximal sections will vary depending on the size of the tracheotomy endotracheal tube, e.g., whether it is intended for use on an adult or a child." (Page 2, para. 34 of the published application). Further, the claimed bends 16, 20 in the tube of the present invention mark the transitions between the sections (distal, intermediate and proximal) of tubing, and dictate the disclosed ratios. These bends 16, 20 correspond to specific parts of the human anatomy, with pre-formed bend 16 conforming to the bend created at the transition between the tracheotomy stoma and the trachea (see page 2, para. 30 of published application), and bend 20 conforming to the bend created at the transition between the stoma and the chest wall of a patient (see page 2, para. 31).

While the differences in the actual size between the pediatric and adult airways can be significant, the overall proportions in upper airway size between adult, pediatric, male and female

airways is basically the same. Proportion refers to the relationship of the vertical to the horizontal dimension, as well as depth. Because average human beings fit within a predictable range of sizes and proportions, the tube of the present invention can be manufactured within the claimed ratios in order to fit all sizes of individuals.

As a result of the foregoing argument, all of the claimed ratios have criticality in the design and function of the tube, so that it can be useful for individuals of all ages. The ratios disclosed in Claims 1, 17, 23 and 26 correspond to these functional features of the tube, and are not a result of simple design choice. Therefore, Applicant respectfully requests that this rejection be withdrawn and the claims be allowed.

CONCLUSION

Applicants believe that each point raised in the pending Final Office Action has been addressed. Therefore, Applicants respectfully request consideration of this application in view of the foregoing remarks and amendments, and that all the instant claims be duly allowed. The Examiner is invited to contact the undersigned directly with any questions or remaining issues regarding the pending claims.

Applicants believe that no additional fee is due as a result of this response.

Respectfully submitted,
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July 6, 2005